REMARKS

Reconsideration and withdrawal of the rejections of this application are respectfully requested in view of the remarks, attachment and amendments herewith.

Claims 41, 42 and 46 are pending in the subject application. Applicants have amended claims 41, 42 and 46 without prejudice. Applicant reserves the right to pursue the subject matter of the canceled claims in one or more divisional applications.

No new matter has been added.

I. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 41, 42 and 46 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (*Office Action* at 2). The rejections are traversed.

Without prejudice and in the interests for facilitating prosecution, Applicants have amended the claims and rendered the rejection moot.

In view of these amendments, Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph rejections.

II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 41, 42 and 46 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/use the invention. The current action articulates the following basis for the rejection:

> 3. Claims 41,42,46 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record. Applicant's remarks have been considered but are not persuasive.
>
> The examiner is not asserting that the specification neither makes nor formulates the compounds of the present invention. Rather the examiner is asserting that the specification does not teach how to inhibit HIV replication or inhibit HIV replication in a mammal with the claimed compound.
>
> The specification does teach how to administer the compound @ page 21 for example. However, contra to applicants assertions, the specification does not teach how to administer the

> compound for the express purpose of inhibiting HIV replication @ page 21 or anywhere else in the specification.
>
> The compounds have been tested to determine binding. However, binding per se is not a patentable utility. Nor is binding indicative of inhibiting HIV replication. Further, contra to applicant's assertions, the reference to page 20 line 3-8 etc all mention 'treatment' and not 'inhibition'. Thus, given the above, the specification does not provide enabling support for inhibiting HIV replication.
>
> The remainder of applicant's arguments regarding state of the art and guidance are all directed to inhibition of HIV replication. These arguments are not persuasive, as the specification does not teach/disclose inhibiting HIV replication.
>
> Reconsideration of all the evidence related to each of the Wands factors, and based on the evidence as a whole, the specification, at the time the application was filed, would not have taught one skilled in the art how make the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510. Thus, undue experimentation will be required to determine if the claimed compound would, in fact, inhibit HIV replication in a mammal.

(*Office Action* at 2-3).

Without prejudice and in the interests for facilitating prosecution, Applicants have amended the claims and rendered the rejection moot. Applicants respectfully submit that the pending claims are fully enabled by the specification.

Applicants now address each of the Wands factors which support a finding that the pending claims are fully enabled.

The Nature of the Invention

The nature of the invention is a method of treating HIV infection in a mammal, wherein the HIV infection is modulated by a CCR5 receptor in the mammal. Applicants believe the invention is fully enabled by the specification for making, formulating, administering, and testing compounds according to the invention for the treatment of HIV infection, as mentioned in Applicants' June 6, 2006 response which is incorporated by reference. For example, the Examiner admits that the specification teaches how to make the compounds of the invention and how to use the compounds of the invention for treatment: "[t]he Examiner is not asserting that the specification neither makes nor formulates the compounds of the present invention . . . [f]urther, contra to applicant's assertions, the reference to page 20 line 3-8 etc all mention 'treatment'. . .". (*Office Action* at 2-3.). Hence, the specification teaches how to make the compounds of the invention and their use for treatment.

The State of the Prior Art and Predictability

Applicants respectfully submit that one of skill in the art would clearly understand the patent specification as providing clear direction in using the compounds of the present invention to treat HIV infection in mammals without undue experimentation. The state of the art at the time of filing, based on the articles provided in Applicants' June 6, 2007 response which is incorporated by reference, indicates that modulating CCR5 would be desirable to treat HIV infection in mammals.

In addition, attached hereto is a copy of the FDA Approved labeling for SELZENTRY™, which is chemically described as N-{(1S)-3-[3-(3-Isopropyl-5-methyl-4H-1,2,4-triazol-4-yl)-*exo*-8-azabicyclo[3.2.1]oct-8-yl]-1-phenylpropyl}-4,4-difluorocyclohexanecarboxamide (Examples 4, 6 and 7 in the specification) (Appendix A). SELZENTRY™ is commercially available and has been FDA-approved for the treatment of CCR5-tropic HIV:

> SELZENTRY, in combination with other antiretroviral agents is indicated for treatment experienced adult patients infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.

(Appendix A at ¶ 1.).

In addition, as indicated in the FDA approved labeling, SELZENTRY™ binds to the human chemokine receptor CCR5 present on the cell membrane, preventing the interaction of HIV-1 gp120 and CCR5 necessary for CCR5 tropic HIV-1 to enter cells. (Appendix A at ¶ 12.4.).

Thus, one of ordinary skill in the art suitably recognizes the nexus between the CCR5 receptor and the treatment of HIV infection as provided in the instant application.

Guidance and Working Examples

As discussed above and in Applicants' June 6, 2007 response, the prior art at the time of filing established a nexus between the CCR5 receptor and treating HIV infection. Applicants also provide herein further compelling evidence that CCR5 antagonism is a viable antiretroviral therapeutic approach as a treatment of HIV infection based on the FDA-approved labeling for SELZENTRY™.

Further, Applicants provided data showing the tested compounds of the invention all yielded an IC_{50} value of less than 10 nM. This data indicates the relatively high potency of the compounds in targeting CCR5 to treat HIV infection.

Based on all of the Wands factors and consideration of the evidence as a whole, it is respectfully submitted that the patent application includes a description of the claimed invention in compliance with § 112, such that the rejection, upon reconsideration, should be withdrawn. In reconsidering whether the patent application includes an enabling disclosure of the claimed invention, the Patent Office must consider all evidence in the record (including the patent application), weighing evidence that confirms enablement against evidence that refutes enablement. See *In re Wands*, 858 F.2d at 737, 740. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the remarks, attachment and amendments, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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